

### **REMARKS**

In the Final Office Action dated November 27, 2008, the Examiner rejected claims 11-18 and 20 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,200,200 to Veech ("Veech"); and rejected claim 19 under 35 U.S.C. § 103(a) as being unpatentable over Veech in view of U.S. Patent No. 5,383,324 to Segers et al. ("Segers").

Applicants respectfully traverse the Examiner's rejection of claims 11-18 and 20 under 35 U.S.C. § 103(a) as being unpatentable over Veech. Veech does not disclose or suggest each and every element of claim 11, for example. The Examiner contends that "[a]lthough it is unclear if Example 2 (column 8) taught by Veech uses a solution of sodium bicarbonate, Veech however suggests doing so in Column 8 Lines 25-26." (Office Action at 5.) Applicants disagree. In fact, it is not "unclear" if Example 2 of Veech teaches using a solution of sodium bicarbonate. It clearly does not. Example 2 of Veech teaches the use of a particulate solid composition in the chamber containing bicarbonate. Veech discloses that "[w]hen the tabs 15 are pulled apart, the two liters of solution in chamber 11 intermixes with the particulate solid composition in chamber 12 and solution readily occurs, thereby to provide the desired two liter dialysis solution which is ready for conventional administration" (emphasis added). (Col. 8, lines 27-31.) Thus, as disclosed in Veech, chamber 11 contains the master batch solution while chamber 12 contains the solid bicarbonate composition before mixing and does not contain an "aqueous sodium bicarbonate component solution," as recited in claim 11. Moreover, column 8, lines 25-26, cited by the Examiner, does not disclose or suggest the use of an aqueous sodium bicarbonate component solution in a separate compartment. This passage of Veech merely discloses that the "charging procedure

employed in Example 1 is repeated and a storable charged bag structure results." (Col. 8, lines 25-26.) As discussed below, Example 1 of Veech does not disclose or suggest the use of an aqueous sodium bicarbonate component solution in a separate compartment, nor does Example 1 disclose the use of two aqueous solutions placed in two different compartments of the same flexible bag assembly, as recited in claim 11.

The Examiner further contends that "[i]n Example 1 Veech teaches . . . a second particulate component (sodium pyruvate) to be charged into the lower compartment of the container. (See column 7, Lines 20-44). The sodium pyruvate is provided in a one-liter solution of water. (See column 7, Lines 36-38.)." (Office Action at 5.) Applicants disagree and respectfully contend that the Examiner has misunderstood the above-referenced portions of Veech. In fact, Veech does not disclose or suggest having an aqueous sodium pyruvate solution in a separate compartment from the master batch solution prior to mixing. Column 7, lines 36-43, a portion of which was cited by the Examiner, discloses that "[s]ufficient crystalline sodium pyruvate is measured to provide 5.1 millimoles per liter thereof in a one liter solution of water, and such crystalline material is charged into the chamber 12 of a container as illustrated above in FIGS. 1 and 2. Thereafter, the chamber 12 is sealed and one liter of the solution above prepared is charged into chamber 11 of such container 10 of FIGS. 1 and 2" (emphasis added). (Col. 7, lines 36-43.) Applicants submit that this passage of Veech indicates that an amount of solid sodium pyruvate is measured, which would provide for a 5.1 mmol/l concentration of sodium pyruvate in one liter of water, and that solid sodium pyruvate alone is placed and sealed in chamber 12 prior to mixing.

There is further support for Applicants' position in the discussion of Example 1 in Veech. Veech further discloses that "[s]ubsequently, the tabs 15 are pulled apart separating the fastener strips 14 from engagement from one another and thereby permitting the solution in chamber 11 to become admixed with the crystalline sodium pyruvate in chamber 12. The crystalline sodium pyruvate readily dissolves in the solution formally contained in chamber 11 so that a single solution results" (emphasis added). (Col. 7, lines 45-51.) The emphasis on the use of the term crystalline in this passage provides further evidence that Veech does not disclose or suggest the use of two aqueous solutions placed in two different compartments of the same flexible bag assembly. Accordingly, Veech does not disclose or suggest "a first predetermined volume of an aqueous sodium bicarbonate component solution, said first predetermined volume being provided in at least one of the at least first and second compartments; and a second predetermined volume of an aqueous acid component solution, said second predetermined volume being provided in at least another of the at least first and second compartments" (emphasis added), as recited in claim 11.

In fact, the Examiner concedes that "Veech does not teach that the particulate mixture to be an aqueous solution." (Office Action at 6.) The Examiner, however, contends that "[i]t would have been obvious to one of ordinary skill in the art at the time of the invention that the particulate mixture could be formulated into an aqueous solution prior to being charged into the lower compartment of the container." (Office Action at 6-7.) The Examiner further contends that "[o]ne would have been motivated to do this because by providing the particulate mixture comprising sodium bicarbonate in an aqueous solution it would make for a more uniform distribution of the particulates

when the two components are mixed for use (See Office Action mailed 6/11/2007, page 7 and 8)." (Office Action at 7.) The Examiner further contends that one skilled in the art would also have been motivated to formulate particulate sodium bicarbonate into an aqueous solution because it would provide a 'ready for conventional intravenous administration' solution (See column 7, lines 54-55)." (Office Action at 6.) Applicants disagree. Veech does not provide any motivation to have an aqueous sodium bicarbonate component solution in a first compartment and an aqueous acid component solution in a second compartment of the same flexible bag assembly, as recited in claim 11. The cited passage of Veech disclosing a "ready for conventional intravenous administration" solution clearly refers to the solution resulting from the mixing of an aqueous batch solution in one compartment and solid crystalline sodium pyruvate in another compartment. (See col. 7, lines 45-54, as discussed above.)

Moreover, Applicants submit that the Examiner has failed to appreciate additional benefits of the claimed invention, and in particular, benefits provided by having two aqueous solutions in separate compartments of the same bag assembly for mixing to form a dialysis liquid that were not disclosed or suggested by Veech. In both example 1 and example 2 disclosed in Veech, the buffer material (e.g., sodium pyruvate or sodium bicarbonate) was in a solid or particulate form, while the material in the separate acid/electrolyte compartment was in a liquid or aqueous form. Accordingly, the carbon dioxide dissolved in the aqueous solution in the acid/electrolyte compartment only serves the benefit of acidifying this aqueous solution. The carbon dioxide does not serve the function of stabilizing the particulate sodium bicarbonate, because in the solid state, sodium bicarbonate is completely stable. As recited in the claimed invention,

however, with the loading of carbon dioxide in the aqueous acid component solution and the presence of an aqueous sodium bicarbonate solution in the other compartment, the carbon dioxide loaded in the acid component solution functions to achieve an equilibrium between two aqueous solutions, wherein the carbon dioxide levels in the aqueous acid component solution and aqueous sodium bicarbonation solution are equal. The carbon dioxide dissociating from the sodium bicarbonate solution does not have any reason to migrate into the aqueous acid component solution compartment to even up the carbon dioxide pressure, because the carbon dioxide pressure equilibrium has already been established before any carbon dioxide has to escape over to the aqueous acid component solution compartment. Thus, because the dissociation of carbon dioxide from the aqueous bicarbonate solution to the aqueous acid component solution is unnecessary and does not occur, the aqueous bicarbonate solution is more stable. Applicants submit that the additional benefit of having a more stable aqueous sodium bicarbonate solution, resulting from each compartment having an aqueous solutions containing carbon dioxide, is another novel aspect of the claimed invention not disclosed or suggested by Veech. Accordingly, for at least the reasons discussed above, Veech does not disclose or suggest having two aqueous solutions in separate compartments of the same bag assembly for mixing to form a dialysis liquid, nor would one of skill in the art be motivated to develop such a structure based on reading Veech. In fact, the disclosed use, in Veech, of a second chamber in a two chamber bag having only solid sodium bicarbonate actually teaches away from the flexible bag of the present invention, as recited in claim 11, for example.

Thus, for at least the reasons discussed above, claim 11 is allowable over Veech. Accordingly, claims 12-20 are allowable at least due to their dependence from allowable claim 11.

Applicants also traverse the Examiner's rejection of claim 19 under 35 U.S.C. § 103(a) as being unpatentable over Veech in view of Segers. Veech in view of Segers does not disclose or suggest each and every element of claim 19. The Examiner contends that "Veech lacks the teaching of the multiple compartment flexible bags being overwrapped in a flexible gas-impermeable plastic material. This deficiency is cured by the teachings of Segers et al." (Office Action at 7.) Applicants disagree. As discussed above with respect to claim 11, Veech fails to disclose or suggest "a first predetermined volume of an aqueous sodium bicarbonate component solution, said first predetermined volume being provided in at least one of the at least first and second compartments; and a second predetermined volume of an aqueous acid component solution, said second predetermined volume being provided in at least another of the at least first and second compartments" (emphasis added). Accordingly, Segers fails to overcome the above-mentioned deficiencies of Veech and claim 11 is allowable over these references. Therefore, claim 19 is allowable over Veech in view of Segers at least due to its dependence from allowable claim 11.

Applicant respectfully requests that this Request for Reconsideration After Final under 37 C.F.R. § 1.116 be considered by the Examiner, placing claims 11-20 in condition for allowance. There are no proposed amendments, and thus the application does not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships were earlier

claimed in the claims as examined. Therefore, this Request for Reconsideration After Final should allow for immediate action by the Examiner.

Furthermore, Applicant respectfully points out that the Final Office Action by the Examiner presented some new arguments as to the patentability of Applicants' claims. It is respectfully submitted that the entry of this Request for Reconsideration After Final would allow the Applicant to reply to the final rejections and place the application in condition for allowance.

In view of the foregoing remarks, Applicant requests the consideration of this Request for Reconsideration After Final, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

If a telephone interview will expedite issuance of this application, the Examiner is requested to call the undersigned at (202) 408-4387 to discuss any remaining issues.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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